

NDA 20789/S-024 and S-026
REMS Modification

NDA 20-789

ZONEGRAN[®] (ZONISAMIDE)

Antiepileptic Drug

Eisai, Inc.
300 Tice Blvd
Woodcliff Lake, NJ 07677

RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOAL(S):

The goal of the REMS is to inform patients of the serious risks associated with Zonegran, including the increased risk of suicidal thoughts and behavior.

II. REMS ELEMENTS:

A. Medication Guide

A Medication Guide will be dispensed with each Zonegran prescription. The Medication Guide will be glued/affixed to the outside of the carton/container. The following language will be prominently displayed on each carton/container to instruct dispensers to provide a Medication Guide with every dispensed prescription of ZONEGRAN:

“Dispense accompanying Medication Guide to each patient.”

A minimum of 4 Medication Guides will be provided per 100-count container of ZONEGRAN (both 25 mg and 100 mg). Each bottle will be outfitted with a hanging outsert containing 4 Medication Guides. The hanging outsert will be attached to the bottle at time of packaging. Medication Guides will be able to be torn off at time of use, leaving the remaining Medication Guides attached to the bottle.

B. Timetable for Submission of Assessments

The REMS was initially approved on April 23, 2009 (NDA 20-789/S-022 and S-025). Eisai will submit REMS Assessments to the FDA by October 23, 2010, by April 23, 2012, and by April 23, 2016, which correspond to 18 months, 3 years, and 7 years from the initial date of approval of the REMS, respectively. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Eisai will submit each assessment so that it will be received by the FDA on or before the due date.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
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NDA-20789	SUPPL-26	EISAI INC	ZONEGRAN 100 MG CAPSULES
NDA-20789	SUPPL-24	EISAI INC	ZONEGRAN 100 MG CAPSULES

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/s/

RUSSELL G KATZ
04/19/2010